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<p>(21) International Application Number: PCT/US00/09034 (22) International Filing Date: 5 April 2000 (05.04.00) (30) Priority Data: 60/127,735 5 April 1999 (05.04.99) US (71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US). (72) Inventors: MIDDLETON, Lance; 1990 Huntington Turnpike, Trumbull, CT 06611 (US). MUHANNA, Nabil, L.; Suite 304, 715 Jesse Jewell Parkway, Gainesville, GA 30505 (US). (74) Agents: GERSHON, Neil, D. et al.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.</p>
<p>(54) Title: ARTIFICIAL SPINAL LIGAMENT</p> <div data-bbox="428 1142 1110 1646"> </div> <p>(57) Abstract</p> <p>A simple and flexible artificial ligament which easily conforms to a patient's anatomy and can be used independently or in combination with an intervertebral graft, implant or prosthesis to return stability to the spine subsequent to a surgical spinal procedure is disclosed. In one preferred embodiment, the artificial ligament (100) is in the form of a flexible conformable plate (102) dimensioned to span adjacent vertebrae and having openings (108) for reception of bone screws, fasteners (110), etc. to mount the plate to the vertebrae. The biomechanical supporting characteristics of the plate approximate the characteristics of the ligament (e.g., anterior spinal) which it replaces thereby providing appropriate support to the spine in extension which also permitting normal spine mobility. A method of supporting adjacent vertebrae with the artificial ligament is also disclosed.</p>		

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ARTIFICIAL SPINAL LIGAMENT

BACKGROUND

1. Field of the Disclosure

5 The present disclosure relates generally to prosthetic members for joining or repairing bone segments, including artificial ligaments and, more specifically, to an artificial ligament intended for partial or full replacement of the anterior longitudinal ligament of the anterior lumbar, thoracic or cervical spine.

2. Discussion of the Prior Art

10 Ligaments extend between adjacent bone structures and serve a primary function of maintaining and providing appropriate stability to the bone structures to maintain the structures in aligned, spaced relation, particularly when subjected to loads in tension or upon torsional movement. Spinal ligaments stabilize and support vertebral bodies during movement of the spine.

15 During surgical treatment of the spine, a section of a spinal ligament may be resected to provide access to a diseased or damaged intervertebral disc and/or to permit introduction of a fusion implant, bone graft or intervertebral disc prosthesis intended for long term support of the vertebral bodies. The bone graft, fusion implant or intervertebral disc return stability to the spinal column in compression and flexing, however, due to
20 removal of the spinal ligament, the biomechanical characteristics of extension and torsional stability lost by the ligament's removal must be replaced. Current techniques involve the

use of metal bone plates which are secured to the vertebral bodies with screw locking mechanisms. Conventional bone plates, however, are rigid and, thus, significantly inhibit spine mobility. Additionally, the screw locking mechanisms utilized with such plates are relatively complicated and provide minimal flexibility with respect to fastener positioning, etc.

SUMMARY

Accordingly, the present disclosure is directed to a simple and flexible artificial ligament which easily conforms to a patient's anatomy and can be used independently or in combination with an intervertebral graft, implant or prosthesis. In one preferred embodiment, an artificial spinal ligament is in the form of a flexible conformable plate dimensioned to span adjacent vertebrae and having openings for reception of bone screws, fasteners, etc. to mount the plate to the vertebrae. The biomechanical supporting characteristics of the plate approximate the characteristics of the ligament (e.g., anterior spinal) which it replaces thereby providing appropriate support to the spine in extension which also permitting normal spine mobility. A method of supporting adjacent vertebrae with the artificial ligament is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described herein with reference to the drawings wherein:

FIG. 1 is a perspective view of the artificial ligament of the present disclosure;

FIG. 2 is a top plan view of the artificial ligament of FIG. 1;

FIG. 3 is a cross-sectional view taken along lines 3-3 of FIG. 2;

FIG. 4 is a perspective view of an alternate embodiment illustrating mounting thereof to the vertebral column;

5 FIG. 5 is a top plan view of an alternate embodiment of FIG. 1;

FIG. 6 is a cross-sectional view taken along lines 6-6 of FIG. 5; and

FIG. 7 is a perspective view of another alternate embodiment of the artificial ligament.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

10 Referring now to the drawings, in which like reference numerals identify similar or identical elements throughout the several views, there is illustrated the artificial ligament of the present disclosure. The artificial ligament of the present disclosure is intended to replace part or all of the supporting function of a ligament previously removed in connection with a surgical procedure. The artificial ligament has particular application

15 in replacing the supportive function of a spinal ligament, e.g., anterior or posterior, which may have been fully or partially resected during a spinal procedure. The artificial ligament is advantageously dimensioned to be positioned to span adjacent vertebrae to restore the natural biomechanics, e.g., including tensional support and range of motion, of the removed ligament segment. The artificial ligament is contemplated for use with a bone

20 graft, fusion implant or artificial disc to compliment the compressive load characteristics of the implant with its tensional supporting capabilities during healing. It is also envisioned that the ligament may be utilized in other capacities such as, for example, repair of other

body ligaments such as the anterior crucial ligament, etc.

Referring initially to FIGS. 1 -3, artificial ligament 100 includes ligament body or plate 102 which is advantageously dimensioned to span at least two adjacent vertebrae. It is envisioned that the ligament body 102 may span three or more vertebral bodies. In a preferred embodiment, the length "l" of ligament body 102 ranges from about 1-3 inches, preferably about 2 inches.

Ligament body 102 is preferably fabricated from a generally flexible material. The selected flexible material of ligament body 102 preferably has physical characteristics which approximate the biomechanical characteristics of the spinal ligament which it replaces. More specifically, the selected material of ligament body 102 supports the spine and provides stability in extension, i.e., the ligament body has tensional load bearing capabilities while also permitting a degree of flexibility approximating the natural ligament. A preferred material of fabrication for ligament body 102 includes a flexible polymeric material such as polyethylene.

Ligament body 102 defines first and second web body end portions 104 connected through intermediate body portion 106. Web body end portions 104 each include a pair of apertures 108 for reception of bone fasteners 110. As best depicted in FIG. 2, apertures 108 may be generally elongated or slotted in the longitudinal direction with respect to longitudinal axis "a" of body 102 to permit multi-position capabilities of the bone fasteners 110 with respect to ligament body 102 and the vertebral bodies as will be discussed. Apertures 108 are preferably countersunk defining a beveled or chamfered surface 112 adjacent the upper surface of the ligament body 102 for reception of the head 114 of the bone fasteners 110 in flush relation therewith. Although two apertures 108 are

shown in each web end portion 104 of the preferred embodiment, it is envisioned that each web portion 104 may have more than two apertures or only one aperture.

With particular reference to FIG. 2, intermediate body portion 106 has a width "w" which is substantially less than the corresponding width of web portion 104.

5 Such dimensioning reduces the transverse profile of ligament body 102 thereby increasing flexibility to facilitate torsional movement of ligament body 102 upon corresponding movement of the patient's spine. The width "w" of intermediate body portion 102 ranges from about .125 inches to about .375 inches, more preferably, about .250 inches.

With reference again to FIG. 1, bone fasteners 110 serve as anchoring
10 means for securing the ligament body 102 to the adjacent vertebrae. The preferred bone fastener 110 includes a fastener head 114 and a fastener shaft 116 extending from the fastener head. The fastener shaft 116 is threaded preferably with a self-tapping thread 118. Upon mounting of bone fastener 110 within the adjacent vertebrae, the fastener head 114 is preferably flush with the upper surface of the ligament body 102. Other anchoring means
15 for mounting ligament body 102 to the vertebral bodies are envisioned by one skilled in the art including expandable bolts, screws, non-threaded fasteners, etc.

In use in connection with an anterior spinal procedure, the anterior ligament is removed to permit access to a diseased or damaged disc section. A partial or full discectomy may be performed followed by insertion of a bone graft, fusion implant (e.g.,
20 as disclosed in U.S. Patent No. 4,961,740, the contents of which are incorporated herein by reference) or an intervertebral prosthesis (such as disclosed in commonly assigned Application Serial No. 09/098,606, filed June 17, 1998, the contents of which are incorporated herein by reference).

When used with fusion devices, the bone fasteners 110 are placed at the outer area 108r of the openings 108 so the ligament is rigid in tension while allowing for compression. This provides for immediate stability in extension as extension loads immediately place the ligament in tension. The fasteners 110 are free to move within openings 108 relative to the ligament 102 in compression. This also permits graft compression.

When used with artificial discs, the fasteners 110 are placed in the middle 108m or inner part 108i of the openings 108 to permit limited relative motion of fasteners 110 within openings 108 of the ligament in both flexion and extension. Extension ultimately leads to tension in the ligament as the fasteners 110 meet the ends 108r of the openings 108. Thus, movement in tension and compression is provided. This flexibility also reduces the likelihood of the fasteners 110 backing out over time.

FIG. 4 illustrates an alternate embodiment of the artificial ligament where intermediate body portion 106 includes an elongated longitudinal depression 120 defining a reduced thickness of ligament body 102. This reduced thickness permits the surgeon to create an additional opening 108 in the ligament body 102 to receive a bone fastener 110 for further fixation to the vertebrae. More specifically, during the surgical procedure the surgeon may create an opening at a desired location within intermediate body portion 106 with a punch or the like. A multitude of openings (shown in phantom) may be formed within depression 120. This feature facilitates use of ligament body 102 in spanning more than two vertebrae, e.g., three vertebrae. FIG. 4 illustrates this embodiment mounted to the spinal column and spanning three (3) vertebral portions " $v_1 - v_3$ " with the middle opening 108 having a fastener for attachment to the intermediate vertebrae " v_2 " and the outer

openings 108 having fasteners 110 mounted to respective vertebrae "v₁", "v₃". Depression 120 preferably also defines a transverse dimension "t" which approximates the diameter of the fastener head 114 to facilitate retention of the head with respect to the ligament body 102.

5 FIGS. 5 and 6 illustrate an alternate embodiment of the artificial ligament 100 of FIG. 1. Artificial ligament 200 is substantially similar to the ligament 100, but, differs primarily in its dimensioning. More specifically, the length "l" of ligament body 102 is shorter than the length "l" of the embodiment of FIG. 1, preferably ranging in length from about 0.75 - 1.25 inches, more preferably about 1.14 inches. In all other respects, the
10 ligament 200 is identical to ligament 100 of FIG. 1.

 FIG. 7 illustrates another alternate embodiment of the ligament of the present disclosure. Ligament 300 includes a slight arcuate bend 302 or bump adjacent its intermediate portion. The arcuate bend provides a degree of excess material to permit the effective length of the ligament to increase when ligament 300 is placed in tensioned, i.e.,
15 the arcuate bend will tend to straighten under extension. The ligament 300 will become increasingly stiffer with a higher tension load. Multiple bends are also envisioned to establish non-linear stiffness.

 While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as
20 exemplifications of preferred embodiments thereof. For example, the present prosthetic device disclosed herein may be implanted to repair a variety of bone structures such as the ankle, knee, wrist, etc. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure.

WHAT IS CLAIMED IS:

1. A flexible prosthesis comprising:

a generally flat, flexible body having end anchoring means on at least two opposed ends for anchoring said body to at least two bone portions and for supporting said body between said at least two bone portions.

2. A flexible prosthesis according to claim 1, wherein said bone portions are vertebrae.

3. A flexible prosthesis according to claim 1, wherein said bone portions are adjacent vertebrae.

4. A flexible prosthesis according to claim 1, wherein said flexible body is supported across at least three vertebrae, and said body is provided with at least one intermediate through-hole aligned with a middle one of said at least three vertebrae and adapted to receive intermediate anchoring means for anchoring said body to said middle one of said vertebrae.

5. A flexible prosthesis according to claim 1, wherein said flexible body is a generally elongated, non-metal body.

6. A flexible prosthesis according to claim 1, wherein said flexible body is adapted to facilitate controlled, relative movement between said bone portions.

7. A flexible prosthesis according to claim 2, wherein said flexible body is adapted to facilitate controlled, relative movement between said vertebrae.

8. A flexible prosthesis according to claim 1, wherein said flexible body is adapted to facilitate fusion between adjacent vertebrae.

5 9. A flexible prosthesis according to claim 1, wherein said flexible body is adapted to be load-bearing in tension and non-load-bearing in compression.

10. A flexible prosthesis according to claim 6, wherein said flexible body is made from a flexible plastic material.

10 11. A flexible prosthesis according to claim 1, wherein said flexible body includes an intermediate bend which, when a predetermined tension load threshold is applied thereto, gradually deforms toward a straightened position and gradually stiffens as tension load increases.

15 12. A flexible prosthesis according to claim 1, wherein said flexible body is supported across at least three vertebrae, and said body is provided with an intermediate through-hole forming section adapted to selectively form one or more through holes therethrough, said through-holes being aligned with a middle one of said at least three vertebrae and adapted to receive intermediate anchoring means for anchoring said body to said middle one of said vertebrae.

13. A flexible prosthesis according to claim 1, wherein said anchoring means are adapted to permit controlled relative movement between said flexible body and said bone portions.

14. A flexible prosthesis according to claim 1, further comprising:
5 at least one intermediate anchoring means positioned between said end anchoring means for anchoring said flexible body to a structure between said bone portions.

15. A flexible prosthesis according to claim 1, wherein each said anchoring means comprise at least one slot on said flexible body and at least one screw
10 adapted to fit through said slot to anchor said body to a respective bone portion.

16. A method of repairing a joint formed by at least two bone sections, said method comprising:

providing a flexible body, having a first end and a second end, across said joint such that said first and second ends are, respectively, aligned with one of said two
15 bone sections; and

anchoring said first and second ends, respectively, to one of said two bone sections to facilitate flexible movement between said two bone sections.

17. A method of repairing a joint according to claim 16, wherein said bone sections are vertebrae.

18. A method according to claim 17, further comprising:

anchoring an intermediate portion of said flexible body to an intermediate vertebra located between the bone sections to which said first and second ends are anchored.

5

19. A method according to claim 16, wherein said flexible body is

anchored to said bone sections in a manner allowing controlled relative movement between said body and said bone sections.

20. A method according to claim 16, further comprising:

10

forming anchoring means on said flexible body at said first and second ends to facilitate anchoring said flexible body to said bone sections.

21. A method according to claim 21, wherein said anchoring means on

said flexible body comprise holes formed in said flexible body.

22. A method of repairing a joint formed by at least two bone sections,

15

said method comprising:

providing a flexible body, having a first end and a second end, across said joint such that said first and second ends are, respectively, aligned with one of said two bone sections;

determining first and second end anchor positions on said first and second bone sections, respectively;

20

forming anchoring holes on said flexible body at positions corresponding,
respectively, to said first and second anchor positions; and

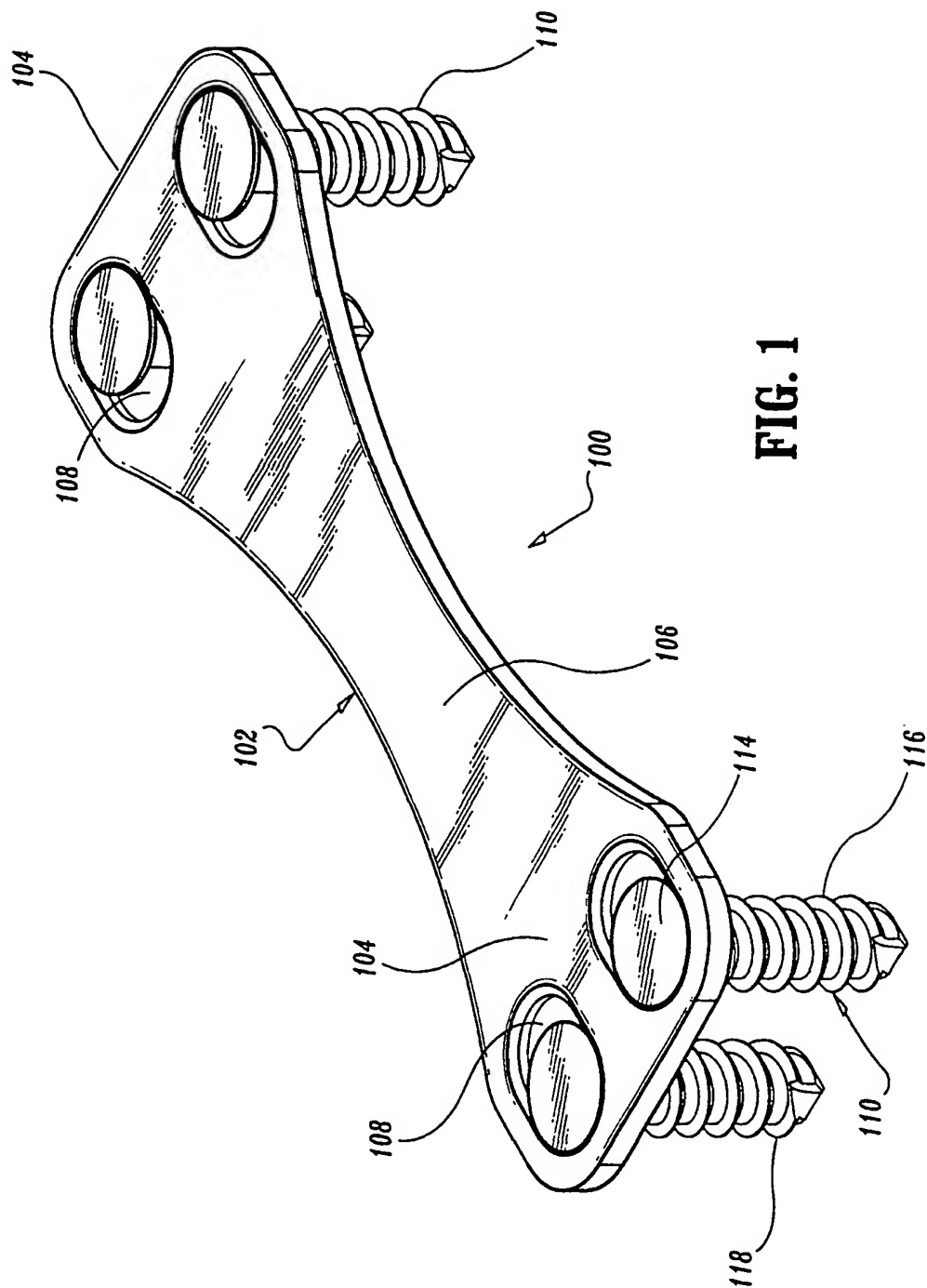
anchoring said first and second ends at said first and second anchor holes,
respectively, using screws, to one of said two bone sections to facilitate flexible movement
5 between said two bone sections.

23. A method according to claim 22, further comprising:

determining at least one intermediate anchor position on between said first
and second bone sections;

forming at least one intermediate anchor hole at a position corresponding to
10 said intermediate anchor position; and

anchoring said flexible body to a structure, using at least one screw, at said
intermediate anchor position.



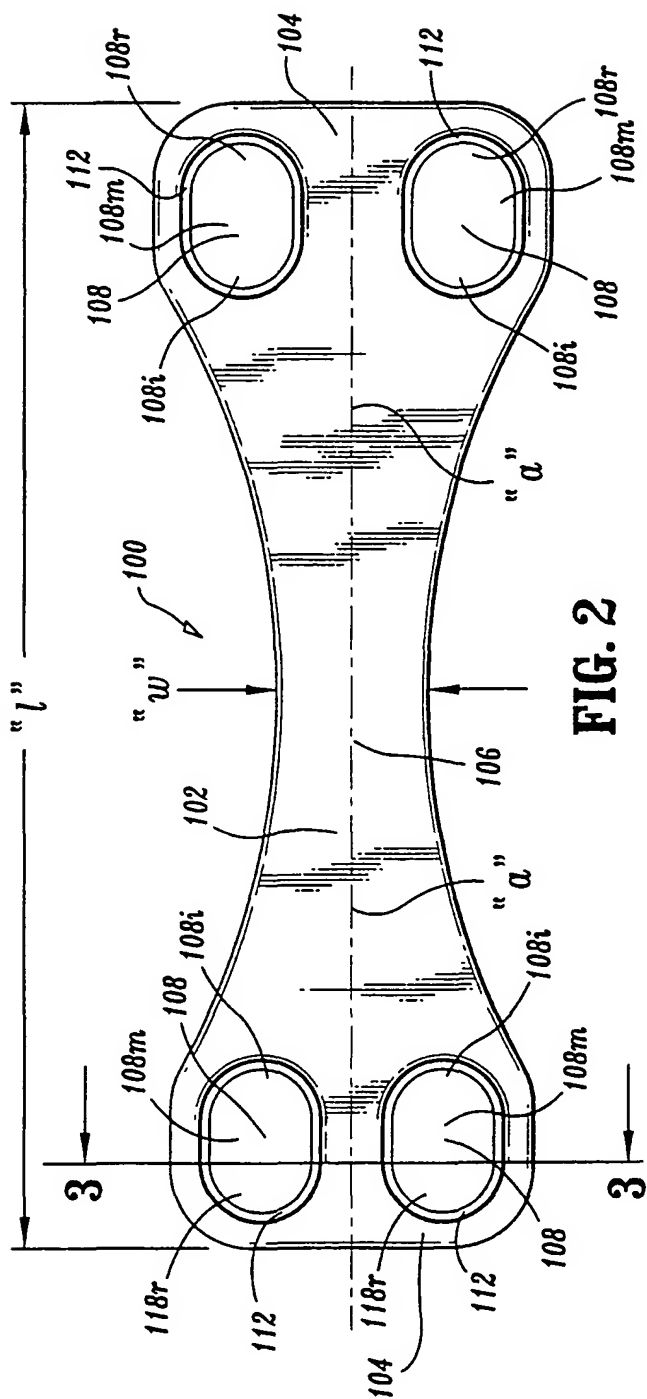


FIG. 2

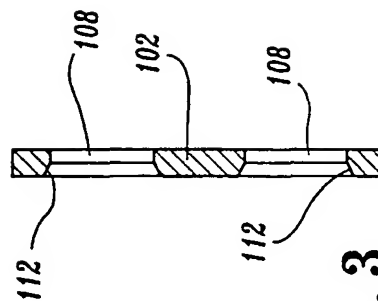
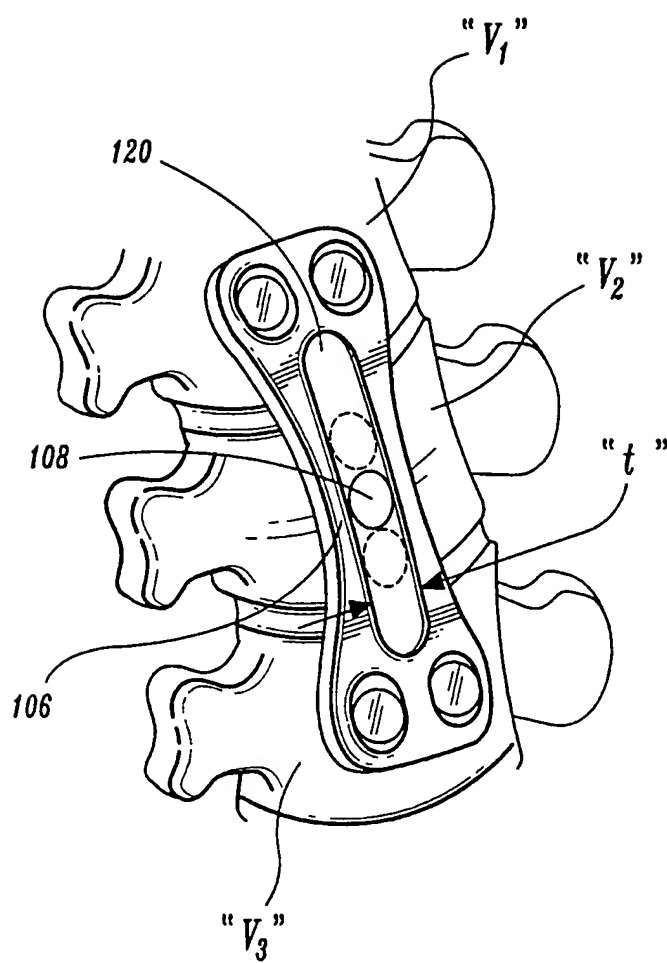


FIG. 3

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**FIG. 4**

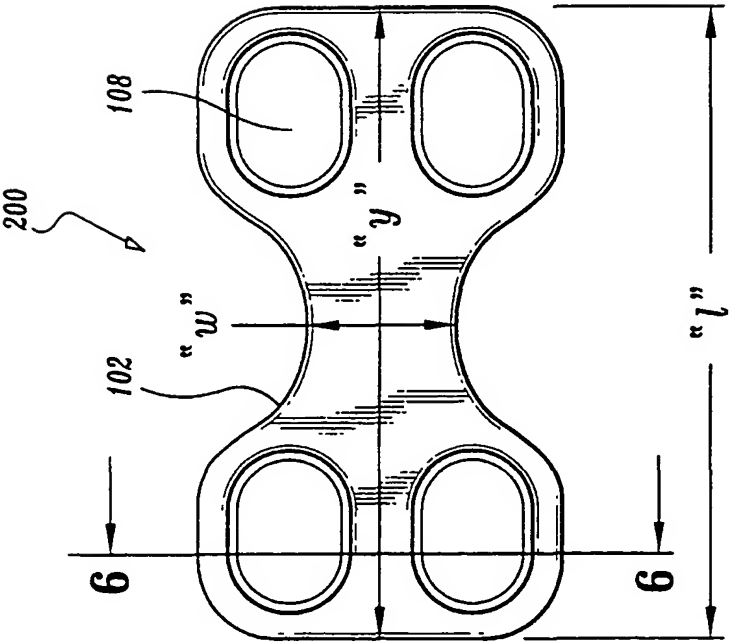


FIG. 5

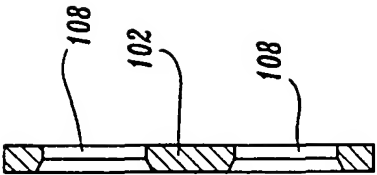


FIG. 6

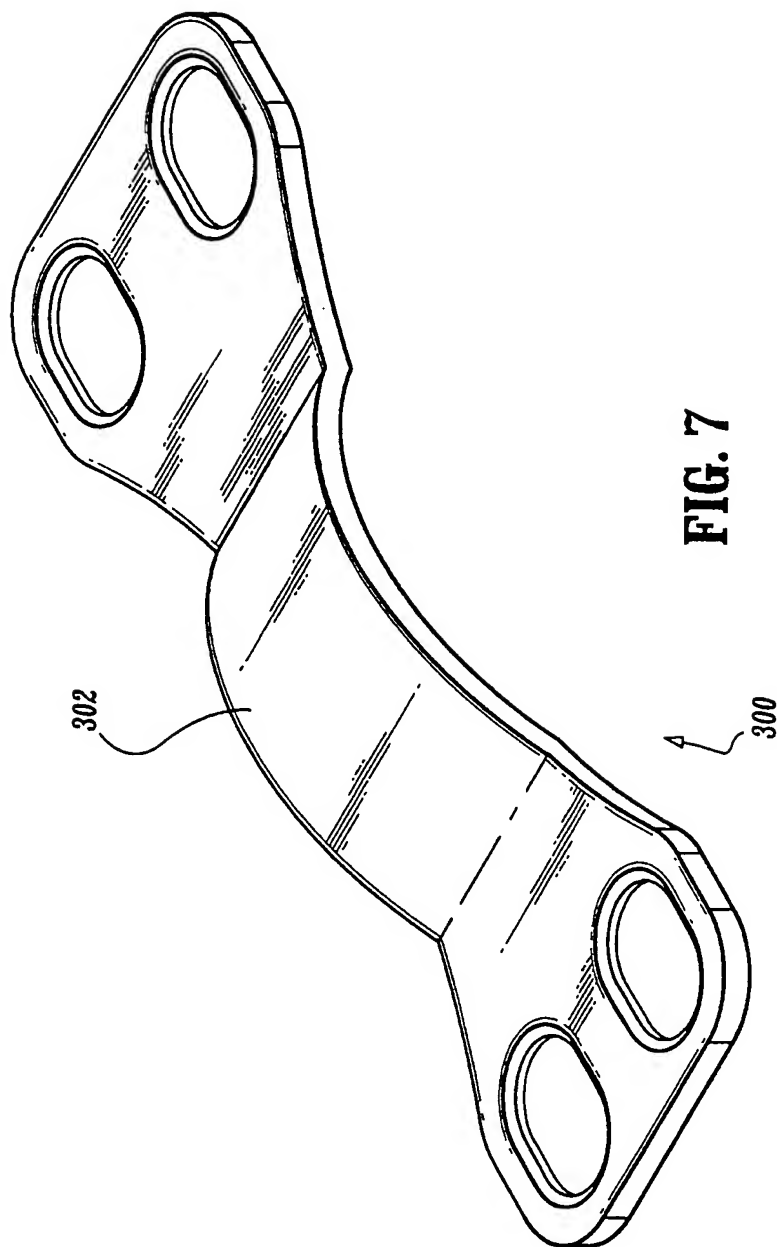


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/09034

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/70 A61F2/28 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 681 310 A (YUAN HANSEN A ET AL) 28 October 1997 (1997-10-28) the whole document ---	1-3, 5-11, 13
X	US 4 773 406 A (SPECTOR MYRON ET AL) 27 September 1988 (1988-09-27) claims; figures ---	1, 5, 6, 9-11, 13-15
X	DE 39 14 164 C (AESCULAP AG) 3 January 1991 (1991-01-03) claims; figures ---	1, 5, 6, 9-11, 13-15
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 July 2000

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20/07/2000

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 403 607 A (WOO SAVIO L-Y ET AL) 13 September 1983 (1983-09-13) column 1, line 6 - line 53 column 3, line 45 -column 6, line 51 column 7, line 16 - line 56 claims; figures 1-5,8,10-13 ---	1,5,6, 9-11, 13-15
X	US 4 403 606 A (WOO SAVIO L-Y ET AL) 13 September 1983 (1983-09-13) claims; figures 1-5,8,10-13 ---	1,5,6, 9-11, 13-15
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